

REMARKS / ARGUMENTS

In the present amendment, claims 1, 3-5, 7, 12-15, 20 and 21 are amended, and claims 8-11 and 16-19 are canceled, with claim 1 and 5 being independent claims. Therefore, claims 1-7, 12-15, 20 and 21 remain pending. Of the pending claims, claims 1-4, 6, 14, 15 and 19 are under consideration, and claims 5, 7, 12, 13, 20 and 21 are withdrawn from consideration.

Applicants note that the claims have been amended to address the 35 U.S.C. 101 rejection, and to place the claims more in accordance with idiomatic English and standard U.S. practice.

Reconsideration and withdrawal of the rejections and allowance of the application are respectfully requested.

Claim of Priority

Applicants respectfully request acknowledgment of the claim of priority to Japanese Application No. 10/277361, filed September 30, 1998, as well as receipt of the certified copy in this national stage application. Applicants note that a Claim of Priority was filed when entering the nation stage on June 25, 2001, and a copy of Form PCT/IB/304 was submitted.

Information Disclosure Statement

Applicants express appreciation for the consideration of the two Information Disclosure Statements, filed on March 27, 2001 and June 25, 2001, by including initialed copies of the Form PTO-1449 submitted therewith.

Response To Restriction Requirement

Applicants note that the Office Action acknowledges Applicants' election with traverse of Group II, claims 4, 6, 10, 11, 14 and 15. Applicants also express appreciation for rejoinder of Group I, whereby an action on the merits of Groups I and II has been provided.

The Examiner has maintained the restriction requirement and made the requirement final with respect to Groups III-VI. In response, Applicants respectfully request reconsideration of the requirement, and at least rejoinder of the nonelected claims, i.e., claims 5, 7, 12, 13, 20 and 21, upon allowance of the elected claims.

Response to Objections

The specification is objected by the Examiner for failing to adhere to the requirements of the sequence rules because the sequences cited in the specification are not marked with SEQ ID NOs.

In response, Applicants have amended the two primer sequences cited in the specification on page 5 by adding the term "SEQ ID NO: 1" and "SEQ ID NO: 2".

The Examiner further asserted that the Title of the Invention is not descriptive and that a new title is required.

In response, Applicants have replaced the Title with the new Title "VPR MUTANT PROTEIN AND ITS ENCODING GENE HAVING APOPTOSIS-INDUCING ACTION".

Rejection under 35 U.S.C. § 101

Claims 1-4, 14 and 15 are rejected under 35 U.S.C. 101 because the claimed invention is asserted to be directed to non-statutory subject matter. The rejection Action asserts that the claimed mutant protein and its encoding gene are naturally occurring.

In response, Applicants note that claim 1 has been amended to recite an isolated protein, and claims 4, 14 and 15 have been amended to recite an isolated apoptosis-inducing gene. Applicants note that this includes proteins for inducing apoptosis, which proteins are not naturally present in an animal, and includes proteins isolated from an animal as well as proteins and genes synthesized artificially in vitro.

Support for the claim amendments appears throughout Applicants' originally filed application, including page 2, line 30 to page 3, line 4, and page 3, lines 19-28, and in the example, starting at page 4, line 30 to page 5, line 32.

Rejection under 35 U.S.C. § 112 , Second Paragraph

Claims 1-4, 6, 8-11 and 14-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

P20825.A18

In response, Applicants initially note that this ground of rejection is stated to apply to a number of claims; however, the body of the rejection only references claim 2. In this regard, the rejection asserts that claim 2 does not further limit independent claim 1.

In contrast to the assertions in the rejection, Applicants respectfully submit that claim 2 includes the deleted 15 amino acids of claim 1, and changes can be made to the protein while maintaining the apoptosis inducing activity.

Moreover, Applicants have amended claim 2 to even more clearly recite the claimed subject matter.

Therefore, applicants respectfully request withdrawal of the rejection of claims 1-4, 6, 8-11 and 14-19 under 35 U.S.C. 112, second paragraph.

Rejection under 35 U.S.C. § 112, First Paragraph

Claims 8-11 and 16-19 are rejected under 35 U.S.C. 112, first paragraph, as it is asserted that the specification does not enable one skilled in the art to make and/or use the claimed invention.

Applicants respectfully submit that the claimed subject matter is enabling to one having ordinary skill in the art. However, to advance prosecution of the application, the claims have been canceled without prejudice to the filing of one or more continuation and/or divisional applications directed to the canceled subject matter. In this regard, Applicants preserve their right to present arguments against this rejection.

Rejection under 35 U.S.C. 102(b)

Claims 1-4, 6, 8-11, and 14-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Stewart et al. (hereinafter "Stewart"), J. Virology 71: 5579-5592, 1997. The rejection asserts that Stewart discloses HIV-1 Vpr truncated 15 amino acids from the C terminal wherein one to several amino acids are substituted, inserted, and deleted and having apoptosis inducing activity and a gene that encodes it. In particular, the rejection references the section "DNA constructs" under "Materials and Methods" of Stewart.

In response, Applicants respectfully submit that the rejection has misinterpreted Stewart. Stewart does not teach a C81 mutant protein as disclosed and claimed by Applicants. The Vpr mutations performed by Stewart are point mutations, that means the replacement of a single amino acid by another. Stewart introduces amino acid substitution at point 30 and point 80 of the Vpr protein, but any deletion of amino acids is not taught.

Accordingly, Stewart does not teach, as recited in Applicants' independent claim 1, an apoptosis inducing agent which comprises an isolated or synthesized in vitro protein as being Vpr protein encoded by Vpr gene of HIV-1 wherein 15 amino acid residues from the C-terminal are deleted.

Moreover, Stewart, does not teach, as recited in Applicants' claim 2, the isolated or synthesized in vitro protein according to claim 1 wherein one to several amino acids are substituted, inserted, and/or deleted, and having apoptosis-inducing activity.

Still further, Stewart does not teach, as recited in Applicants' claim 3, an

P20825.A18

apoptosis inducing agent according to claim 2, which comprises said protein having substantially no ability of arresting a cell in G₂ phase.

Still further, Steward does not teach, as recited in Applicants' claim 4, 14 and 15 an isolated or synthesized in vitro apoptosis-inducing gene encoding the protein according to any of claims 1, 2 and 3.

Still further, Steward does not teach, as recited in Applicants' claim 6, a recombinant vector containing the gene according to claim 4.

Still further, Steward does not teach, as recited in Applicants' claim 7, a method for inducing apoptosis of a cell by introducing the recombinant vector according to claim 6.

Applicants therefore, respectfully submit that Stewart does not teach Applicant's invention and the rejection of claims 1-4, 6, 8-11, and 14-19 as anticipated by Stewart should be withdrawn.

P20825.A18

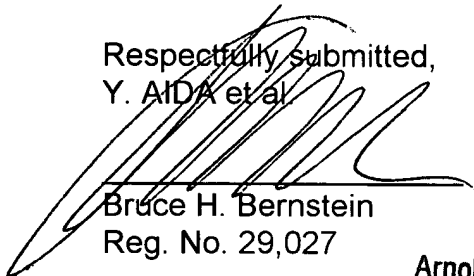
CONCLUSION

In view of the forgoing, the Examiner is respectfully requested to reconsider and withdraw the rejection of record, and allow all the pending claims.

Allowance of the application is requested , with an early mailing of the Notices of Allowance and Allowability.

If the Examiner has any questions or wish to further discuss this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully Submitted,
Y. AIDA et al



Bruce H. Bernstein
Reg. No. 29,027

May 04, 2005
GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
(703) 716-1191

Arnold Turk
Reg. No. 33,094